PATENT
Attorney Docket **056707-5009-01**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **Gregory M. Glenn *et al.***	)	
U.S. Application No. **10/633,626**	)	Group Art Unit: **1644**
Filed: **August 5, 2003**	)	Examiner: **Yunsoo Kim**
For: **Dry Formulation for Transcutaneous Immunization**	)	

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, **Mail Stop Amendment**
Randolph Building
401 Dulany Street
Alexandria, VA 22314

DECLARATION UNDER 37 C.F.R. § 1.132

I, the undersigned, Diane Epperson, do hereby declare that:

1. I am a citizen of the United States, residing at 6501 Brookes Hill Ct., Bethesda, Maryland.

2. I have been awarded a doctorate in Immunology from Harvard University. I did my postdoctoral training in Immunology, Molecular Immunology and Cancer Immunotherapy at Yale University and the National Institutes of Health.

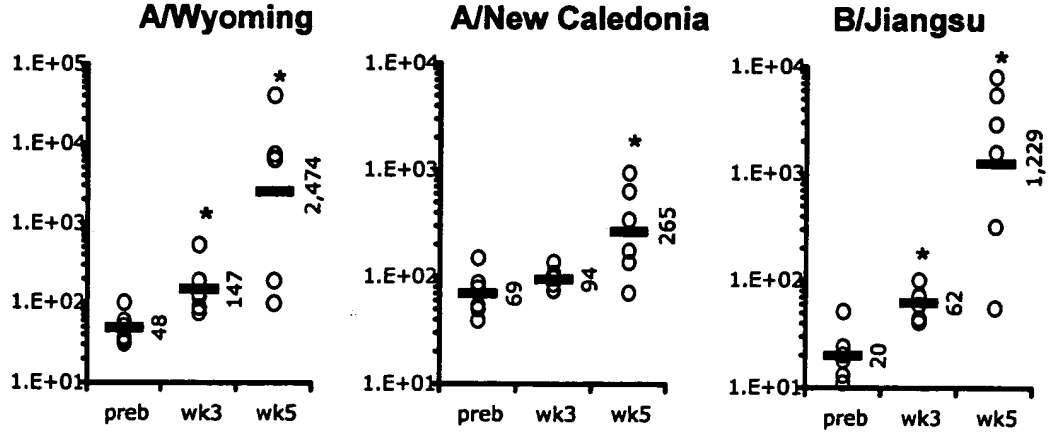
3. I have been employed by Iomai Corporation, since November, 2001 and I am presently the Manager of Pre-clinical Immunolgy at Iomai Corporation. During my employment at Iomai Corporation, I have been engaged in research and development in the area of skin immunization and cancer immunotherapy.

4. I am familiar with the specification and pending claims of U.S. Patent Application No. 10/633,626. I have reviewed the Office Action, mailed January 10, 2006. I believe that the specification enables the scope of the claims in view of the following experimental data performed at Iomai Corporation:

The experiment was established to investigate whether an antigen delivered by transcutaneous immunization in the absence of hydration or pretreatment of the skin can induce an immune response.

In this experiment guinea pigs were carefully shaved to expose the skin immediately before the addition of the patch. No skin manipulations were performed. There was no hydration or pretreatment of the skin. A dry formulated patch comprised of trivalent influenza split virus containing 15ug of hemagglutinin (5ug A/Wyoming strain, 5ug A/New Caledonia strain, and 5ug B/Jiangsu strain) was placed on the skin and worn overnight. The animals were given two immunizations via a patch. The first was at day 1 and the second on day 22.

The results of the experiment are shown in the following graphs. The results indicate that titers to the three influenza strains increased over the antibody titers before immunization.



Geomeans from each time point (n=6 animals) are signified by a bar and the given to the right of each bar. An * denotes titers that are statistically greater ($p<0.05$) than the pre-bleed titers from the same animals by two-tailed students T-test.

Titers to all three immunizing influenza strains rose above the titers in the same animals before immunization (pre-bleed). The week 3 titers reflect the immune response after one

immunization; the week 5 titers reflect the immune response after two immunizations. The titers rose after each immunization for each strain. The results establish that we can induce an immune response in animals by applying to their skin a dry formulation comprising immunizing antigens without hydrating or disrupting the stratum corneum prior to applying the dry formulation.

5. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 5/1/06 By: Diane E. Epperson

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DECLARATION UNDER 37 C.F.R. § 1.132

I, the undersigned, Gregory Glenn, do hereby declare that:

1. I am a citizen of the United States, residing at 14525 Montevideo Rd., Poolesville, Maryland 20837.

2. I have been awarded Doctor of Medicine from the Oral Roberts University School of Medicine, Tulsa, Oklahoma. I did my residency at Miami Children's Hospital, Miami, Florida. I did my training in research at The Walter Reed Army Institute of Research, Washington, D.C.

3. I have been employed by Iomai Corporation, since 1997 and I am presently the Sr. Vice President & Chief Scientific Officer at Iomai Corporation. During my employment at Iomai Corporation, I have been engaged in research and development in the area of vaccines.

4. I am familiar with the specification and pending claims of U.S. Patent Application No. 10/633,626. I have reviewed the Office Action, dated January 10, 2006, and the Advisory Action, dated June 5, 2006. I believe that the specification enables the scope of the claims in view of the following experimental data performed at Iomai Corporation:

This experiment was established to investigate whether an antigen delivered by transcutaneous immunization without pretreatment of the skin can induce an immune response.

A 50μg LT dry patch was placed on upper deltoid skin that had no pretreatment, shaving or any manipulation. Patients wore the patch for 6 hours and the patch was removed.

Sera were collected at day 0, 7, 14, and 21. Antibody titers were measured by performing an ELISA. The results of the experiment are shown in Table 1.

Table 1. Anti-LT IgG immune responses to Dry Patches placed on skin without pretreatment, reported as anti-LT IgG (ELISA Units) and fold rise over day

Subject	Day 0	Day 7	Day 14	Day 21	# Fold Rise at D7	# Fold Rise at D14	# Fold Rise at D21
156	1906	3755	4217	4026	2	2	2
221	283	500	528	535	2	2	2

Table 1 shows that subject number 156 and number 221 developed anti-LT immune responses. Based on assay sensitivity, a 2 fold rise indicates a seroconversion. The results demonstrate that LT delivered by transcutaneous immunization without pretreatment or hydration of the skin induced an immune response. These results are consistent with previous findings in which simple wet gauze patches containing LT applied to patients induced robust LT antibody responses (Glenn *et al*, Nature Medicine, 2000).

Thus, these results provide further support that the present specification enables a method of inducing an immune response by applying a dry formulation to the skin of a subject without pretreatment, such as shaving or any manipulation of the skin.

5. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 10 Oct 06 By: _____

Gregory Glenn, M.D.